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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/961,400
Filing Date	September 25, 2001
First Named Inventor	Rybak
Group Art Unit	unknown
Examiner Name	unknown
Total Number of Pages in This Submission: 7	Attorney Docket Number: 015280-343200US

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  - **(1)-Protest Under 37 CFR 1.291 w/attachment WO 99/50398**
  - **(2)-Return Postcard**

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Jean M. Lockyer Reg. No. 44,879
Signature	Jean M. Lockyer
Date	September 17, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date: September 17, 2002

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SF 1386501 v1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: Unknown
Rybak *et al.*	Art Unit: Unknown
Application No.: 09/961,400	PROTEST UNDER 37 C.F.R. § 1.291
Filed: September 25, 2001	
For: IMMUNOCONJUGATES OF TOXINS, DIRECTED AGAINST MALIGNANT CELLS	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The above-referenced application is hereby protested under 37 C.F.R. § 1.291. This protest is submitted prior to the publication of the application. A copy of the protest has been served on the Applicant. Proof of service is attached hereto. The Protestors submit that the inventors named in the instant application are not the correct inventors, as one of the inventors, Dr. David M. Goldenberg, is not a co-inventor of the claimed subject matter. Therefore substantial issues relating to patentability are raised under 35 U.S.C. § 102(f) and 102(g).

The protested application was filed as a divisional of U.S. serial number 09/622,613 (the '613 application) and names Drs. Rybak, Newton, and Goldenberg as inventors. The claims are directed to the combination of analogs of a cytotoxic frog ribonuclease (RNase) and an antibody to a B-cell, *e.g.*, LL2. As explained below, Dr.

Goldenberg contributed to the generic invention of such an RNase and an LL2 antibody. However, co-inventorship of the generic conjugates does not entitle him to claim co-inventorship of the particular conjugates comprising the novel, unobvious RNase analogs disclosed in the instant application. The protestors submit that Dr. Goldenberg is not a proper inventor, as the aspect of the invention that is novel and un-obvious over the prior art, *i.e.,* the new RNase analogs, was developed solely by Drs. Rybak and Newton.

Background

The parent '613 application is a U.S. national phase application of WO/99/50398. The '613 application names Drs. Susanna Rybak and Diane Newton as co-inventors. The application claims the benefit of priority of U.S. serial number 60/079,751 ('751), which has a filing date of March 27, 1998. The provisional application also names Drs. Rybak and Newton as inventors. The invention disclosed in the '613 and '751 applications is based upon the discovery of novel and unobvious analogs of a cytotoxic ribonuclease from frog. The claims in the '613 application as filed are directed to the analogs per se, analogs conjugated to targeting moieties, and their therapeutic uses. When the provisional application was originally filed in 1998, Drs. Rybak and Newton disclosed the combination of the novel, unobvious analogs they invented conjugated to antibodies against B-cells. A specific B-cell antibody, LL2, belonging to Immunomedics Corporation of Morris, New Jersey, was described and claimed. A copy of the WO publication, corresponding to the parent '613 application and claims, is attached.

The prior art to the '398 application includes the original discovery of the RNase ONCONASE®, various analogs to ONCONASE (*e.g.,* WO97/31116, published August 28, 1997) and its cytotoxic properties. The art also includes PCT application WO 98/5043 (U.S. Patent 6,395,276 is an issued patent in the same family), which was filed on May 1, 1998, and has a priority claim of May 2, 1997. This application names Drs. Rybak, Newton, and Goldenberg as co-inventors. The invention disclosed therein encompasses an onconase, *i.e.,* a broadly defined cytotoxic ribonuclease, *e.g.,*

ONCONASE®, in combination with an antibody directed to a B-cell, *i.e.,* LL2. Drs. Rybak, Newton, and Goldenberg were co-inventors to the combination of LL2 and an onconase. However, Dr. Goldenberg is not a co-inventor of the subject matter claimed in the instant application as he did not contribute to the conception of the invention, nor did he contribute to an aspect of the invention that makes it patentable.

An inventor's contribution should make the invention patentable

In an unpublished case (*Levin v. Septodont*, 2002 U.S. App. Lexis 7359), the Federal Circuit reviewed the standards for joint inventorship. A joint invention is "the product of a collaboration between two or more persons working together to solve the problem addressed." *Burroughs Wellcome Co. v. Barr Lab., Inc.,* 40 F.3d 1223, 1227 (Fed. Cir. 1994). A joint inventor must (1) contribute in some significant manner to the conception or reduction to practice of the invention (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art (*Pannu v. Iolab Corp.* 155 F.3d 1344, 1351 (Fed. Circ. 1998). In *Levin*, the Court further explained that the significance of an alleged joint inventor's contribution should be assessed by asking whether the contribution helped to make the invention patentable, citing *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Circ. 1997) and *Garrett Corp. v. United States,* 190 Ct. Cl. 858, 422 F.2d 874 (Ct. Cl. 1970).

The inventorship issue in *Hess* involve an engineer who argued that he should have been named as a co-inventor of a balloon angioplasty catheter. He had suggested that the named inventors employ a special tubing. The named inventors accepted this suggestion and the patent for the catheter explicitly refers to the particular tubing. Even though the engineer's contribution to the patented catheter appears in the claims, the Federal Circuit ruled that he was not an inventor because he was only explaining the state of the art and supplying a product for use in their invention.

In *Garrett*, the court considered whether a claim was invalid for failure to join an inventor. The claim at issue was drawn to a boarding ramp for inflatable life rafts. The evidence of the alleged co-inventor's contribution was unclear, but the court assumed for argument's sake that he had "suggested the broad idea of a water ballast pocket for use in conjunction with the boarding ramp." *Id.* at 881. Even though the language of the claim for the boarding ramp included "a water ballast pocket", the court held that the person who suggested the idea was not a joint inventor because that idea was obvious in view of the prior art. Because the named inventor had conceived and developed the only non-obvious feature of the claim, the court concluded that he was the sole inventor. Similarly, in *Levin*, the Federal Circuit determined that the appearance of ingredients suggested by an alleged co-inventor in the claims of the patent at issue was not sufficient to make him a joint inventor under *Pannu* because the contributions did not help to make the claimed subject matter patentable.

Indeed, as the Court explained in *Levin,* consideration of the basic principles of patent law also supports the conclusion that a person does not qualify as an inventor simply because his contribution appears in the language of the patent's claims. The Court noted that because a patentable invention need not be novel and non-obvious in every respect, it logically follows that many elements of an invention described in a patent claim will be neither novel or non-obvious. They concluded that it would be implausible to say that a person who contributed only a non-novel and/or obvious element of a claim can be called an inventor.

The novel and unobvious analogs render the claimed conjugates novel and unobvious

In the protested application, the novel and unobvious analogs are the elements of the claims that render them patentable over the known genus of an RNase molecule attached to an LL2 antibody. The analogs are the invention of Drs. Newton and Rybak, not Dr. Goldstein. Accordingly, in view of the standards of inventorship set forth by the courts, Dr. Goldstein is not a co-inventor of the claimed subject matter. Thus, Drs.

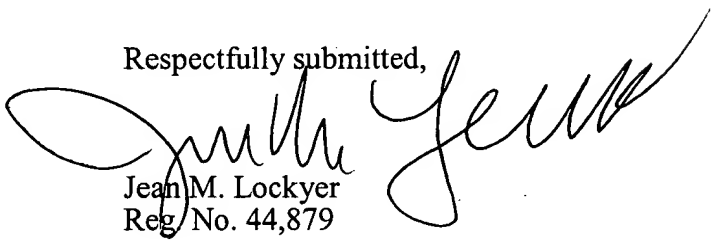
Rybak and Newton are the sole inventors of not only the analogs themselves, but of the combination of the new analogs and an LL2 antibody.

Lastly, as expressed by the Federal Circuit in *Burroughs Wellcome*, "conception of invention is complete only when idea is so clearly defined in inventor's mind that only ordinary skill would be necessary to reduce invention to practice" (*Burroughs Wellcome* at page 1223). Although the idea of a genus of RNases conjugated to LL2 might have been complete in the minds of Drs. Newton, Rybak, and Goldenberg; Dr. Goldenberg had no knowledge of the new analogs. It therefore follows that the invention can only have been complete in the minds of Drs. Rybak and Newton. How then, could Dr. Goldenberg be a co-inventor of the invention claimed in the protested application, *i.e.*, conjugates comprising the novel, unobvious analogs conjugated to LL2?

Conclusion

For the reasons set forth above, Dr. Goldenberg is not an inventor of the subject matter claimed in the instant application. Thus, substantial issues of patentability are raised under 102(f) and 102(g).

Respectfully submitted,



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PROOF OF SERVICE

I hereby certify that, on the 17th day of September, 2002, a true copy of the foregoing PROTEST UNDER 37 C.F.R. §1.291 was forwarded by first class mail to counsel for the applicant as follows:

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